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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,887	11/20/2001	Susana Salceda	DEX-0269	3405
26259	7590	05/14/2004	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			HORLICK, KENNETH R	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/001,887	Applicant(s) SALCEDA ET AL.	
	Examiner Kenneth R Horlick	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5,7-9,15 and 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 7-9, 15, and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claim 15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "means for determining the presence of the nucleic acid molecule of claim 1" is vague and indefinite because such means are not clearly defined. While this claim appears to invoke "means plus function" language according to 35 U.S.C. 112, 6th paragraph, it cannot be determined from the specification what means are contemplated.

2. With respect to the above rejection, the arguments of the response filed 03/01/04 on pages 14-15 have been fully considered, but are not found persuasive. While the response points to pages 95 and 96 for support of the claim language, it is maintained that these general descriptions of various methodologies do not in fact define any "means" which can be understood by one of ordinary skill in the art, nor is there any basis for searching the prior art for such unclear "means". Thus, the rejection is maintained.

3. Claims 1, 2, 4, 5, 7-9, 15, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection applies to the claims insofar as the embodiments in claim 1 of (c), (d), and (f); that is, nucleic acids which: have at least 90% sequence identity to the nucleic acid molecule of (a) or (b) and hybridize under stringent conditions to said molecule; have at least 60%

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sequence identity over their entire length to said molecule; and encode an amino acid sequence having at least 90% sequence identity to SEQ ID NO:127. Although the specification only discloses the sequence of SEQ ID NO:63 or 64, these embodiments cover a large genus of related nucleic acids which are not described and were not in applicant's possession. Included in this genus are any number of nucleic acids which have some sequence homology with SEQ ID NO:63 or 64, but nonetheless have substantially different and unpredictable properties, such as encoding a polypeptide of substantially or completely different biological function. Thus, the specification does not have written descriptive support for the large genus as set forth in parts (c), (d), and (f) of claim 1.

4. With respect to the above rejection, the arguments of the response filed 03/01/04 on pages 15-17 have been fully considered, but are not found persuasive. The response argues that "upon discovery of the instant claimed nucleic acid sequence...and its expression, applicants were clearly in possession of additional nucleic acid sequences identified in accordance with routine procedures based upon this reference sequence. Further, the instant specification and its teachings clearly place the public in possession of these sequences as well." However, the Office does not agree with this position; it appears that the arguments of the response might be applicable in the case of 112, 1st paragraph enablement considerations, but the issue at hand concerns written description and possession at the time of filing. Contrary to the conclusion of the response, it is maintained that applicants were only in possession of the nucleic acid of SEQ ID NO:63 or 64 and nucleic acids encoding the same amino acid sequence (SEQ ID NO:127) at filing. While in some cases it may be possible to claim a nucleic acid more broadly than a single

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disclosed species given a certain degree of identity or hybridization conditions and a function, in the instant case “detectably expressed in breast tumor tissues” is not considered a function.

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, 4, 5, 7-9, 15, and 18-20 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The instant application does not disclose a specific, substantial, and credible utility for the nucleic acid sequence mentioned in the claims. The instant application does not disclose a connection between presence or expression of SEQ ID NO:63/64 and breast cancer. For example, none of the tables on pages 116-124 shows such a nexus. The demonstration of expression of a sequence in a specific tissue type cannot be translated to mean that that sequence is necessarily a marker for cancer in that tissue. In addition, the application does not disclose or teach the meaning or significance of any particular assay for expression of SEQ ID NO:63/64. Thus, the instant application does not disclose a specific, substantial, and credible utility for SEQ ID NO:63/64, nor is there a readily apparent utility under 35 U.S.C. 101 for SEQ ID NO:63/64.

Claims 1, 2, 4, 5, 7-9, 15, and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and/or use the invention. The discussion in the rejection under 35 U.S.C. 101 is incorporated here.

6. With respect to the above rejection, the arguments of the response filed 03/01/04 on pages 18-19 have been fully considered, but are not found persuasive. The response argues that provisional application 60/249,998 “sets forth mRNA subtraction experiments in breast tissue demonstrating differential expression of these markers in breast cancer as compared to normal tissue. Figure 20 (SEQ ID NO:2) of this provisional application is identical to SEQ ID NO:63 of the instant application.” However, as is the case in the instant application, this mention of Figure 20 in said provisional application and its sequence corresponding to instant SEQ ID NO:63, along with mention of general “mRNA subtraction experiments” with respect to “these markers”, does not demonstrate a nexus specifically between SEQ ID NO:63/64 and differential expression in breast cancer. It is unclear what “these markers” refers to in the provisional application. Thus, if applicants believe such a specific nexus is established in 60/249,998, it is requested that this be more clearly pointed out.

7. Claims 1, 2, 4, 5, 7-9, 15, and 18-20 are free of the prior art, but are rejected for other reasons. No claims are allowable.

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8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

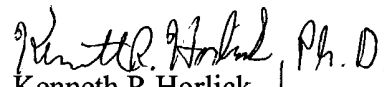
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 571-272-0784. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Kenneth R Horlick
Primary Examiner
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05/04/04